Washington State Medical Test Site Rules
PRE-INSPECTION SELF-ASSESSMENT CHECKLIST

HEMATOLOGY/COAGULATION TESTS - MODERATE COMPLEXITY ONLY

SPECIALTY: Hematology

TEST COMPLEXITY: Moderate

Examples of tests: CBCs performed on instruments classified as moderate complexity; automated differential; manual WBC differential procedures with no interpretation of morphology or identification of atypical cells; smears for granulocytes; manual reticulocyte count; semen examination for presence or absence of sperm; prothrombin time; activated partial thromboplastin time; and fibrinogen tests performed on instruments classified as moderate complexity. Test complexity listing is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

PROFICIENCY TESTING:

Proficiency testing is required for analytes specified in 42 CFR 493.801 – 493.959. For hematology these tests are:

Cell Identification	Auto or Manual WBC differential
Erythrocyte count (RBC)	Hematocrit
Hemoglobin	Leukocyte count (WBC)
Platelet count	Fibrinogen
Partial thromboplastin time (APTT)	Prothrombin time

Biannual verification of the accuracy of the test is required for all tests that are not waived and are not on the list of tests for which proficiency testing is required.

PERSONNEL – MODERATE COMPLEXITY TESTING

___ The director, technical consultant, clinical consultant and testing personnel meet personnel qualifications for moderate complexity testing [42 CFR Part 493.1403 - 1425 subpart M (CLIA) – Available from the LQA Office – see Part III of initial MTS application]

___ Documentation of personnel education, experience, training for the testing performed

___ Annual documentation of the assessment of personnel competence

___ Documentation that training is provided to personnel when problems are identified

___ Written laboratory safety policies and evidence that staff adhere to them

QUALITY CONTROL

___ Procedures are written for specimen collection and handling, test performance, reporting of results, quality control and quality assurance

___ Technical procedures include principle, specimen required, equipment/reagents needed, directions for performing the test, (including slide preparation and examination), sources of error, interpretation of results (includes criteria for repeating/referring specimens for further review), reporting protocol and references

___ Test kits and reagents are correctly labeled, stored at the proper temperatures and used within expiration dates

___ Documentation that equipment/ procedure calibration done as required by manufacturer and when controls show trends, shifts or are out of limits and other corrective action has not fixed the problem Calibration check every 6 months; worksheets, printouts, tapes available for most recent two years

___ Documentation of new instrument/test validation studies available

___ Reference ranges established/verified for control materials and documentation available

___ Patient reference ranges available and verified

___ Documentation that appropriate quality control has been performed, evaluated for shifts and trends and reviewed (for automated blood counts 2 different levels every 8 hours of testing; for manual blood counts 1 level each 8 hours of testing; for qualitative tests a positive and a negative reference material each day of testing; for coag tests 2 different levels every 8 hours and when any reagent changed

___ Reference books / atlases available for identification of unknowns

___ Equipment maintenance performed as appropriate and documented

___ Corrective actions documented

___ Documentation that reagents prepared/stored and used at proper temperatures

QUALITY ASSURANCE

___ Written quality assurance plan available

___ Quality assurance policies written and evidence of evaluation and review of quality control results, proficiency testing results, biannual verification of accuracy of tests, quality assurance activities and patient test results available

___ Written policies for how problems identified and complaints handled and instructions for documenting and correcting problems and resolving complaints and any other remedial actions taken

___ Written instructions for specimen collection, handling, preservation and transportation

___ Written criteria for accepting and rejecting specimens

___ Policies written defining critical values, reporting critical results and corrected reports

___ Refer specimens only to a lab with valid medical test site license or meeting equivalent HCFA requirements

___ Procedure for providing clients updates of testing changes that would affect test results or their interpretation

___ Adequate space and facilities available

___ Local, state and federal regulations for infection control, hazardous/infectious waste disposal adhered to and documented

RECORDS

___ Patient test orders include: patient name or identifier, person ordering the test, date and time of specimen collection, and patient age and sex if appropriate

___ Test records include date sample collected, date tested and identification of person who performed test

___ Test reports include: name and address of where tests were performed, patient name or identifier, date (and time, if appropriate) results reported, unit of measure for each value, specimen limitations and normal ranges

___ Equipment function checks kept 2 years and maintenance records for life of instrument

___ Lot numbers, expiration dates of kits, reagents, controls, calibrators, standards kept 2 years

___ Records kept for 2 years: requisitions, testing records, patient reports of results, quality control results, proficiency testing data; biannual verification of accuracy of tests, quality assurance activities